STATEMENT FOR THE RECORD

of

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"Anthrax Protection: Progress or Problems"

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INTRODUCTION

Good afternoon, Chairman Shays, Ranking Member Kucinich, and distinguished members of the Committee. It is a pleasure to be with you today to discuss the role of the Science and Technology Directorate (S&T) of the Department of Homeland Security (DHS) in detection of various biological threat agents, specifically anthrax.

As this committee and many of our Nation's leaders recognize, the threat of a biological attack is a very real and grave concern. Advancements in science and technology play a vital role in protecting our Nation from such an attack. We, DHS S&T, are committed to developing robust technologies and processes to more effectively and accurately detect the presence of anthrax and other biological threat agents both within buildings and the outdoor environment.

The anthrax attacks of 2001 left a wave of fear and disruption in their path and made our Nation and government realize that a more concerted effort was needed to prevent future impacts, more effectively manage the consequences of such an event, and mitigate their impact. The various components of the newly formed Department of Homeland Security assumed this challenge and took a broad systems wide approach to the problem that, among other outcomes, determined that earlier attack warning translated into saved lives. While ideally an attack will be detected and interdicted prior to its execution, we must be prepared to both detect and respond appropriately and expeditiously so that we can protect our people, economic base and critical infrastructures. Environmental sampling is a key, far-reaching component for the detection and surveillance of biological threat agents, the incident characterization subsequent to the release, and validation that a contaminated area has been successfully remediated. Therefore, environmental detection and sampling for biological threat agents has an integral and crucial role in our overarching national biodefense strategy. In the President's *Biodefense for the 21st Century* (Homeland Security Presidential Directive 10), DHS is charged to develop, in coordination with other applicable Federal departments and agencies, an integrated and comprehensive attack warning system that rapidly recognizes and characterizes the dispersal of biological agents in human and animal populations, food, water, agriculture, and the environment. Furthermore, DHS as been designated as the lead Federal agency, in coordination with other appropriate Federal departments and agencies, to protect critical infrastructures, and will therefore work to develop and deploy biodetection technologies and decontamination methodologies. Additionally, HSPD-10/NSPD-33, the President's *Biodefense for the 21st Century*, assigns DHS to act in an integral supporting role with EPA, who has the overall lead in decontamination.

DHS has been actively addressing these issues and has made significant progress. Highlights to be presented in this testimony include:

- Biological surveillance and detection, including facility biomonitoring, incident characterization, and associated technology improvements
- Restoration of biologically contaminated facilities, highlighting partnerships with transportation hubs, as well as other local, state, and Federal agencies

- Leadership and coordination of interagency efforts for surveillance, detection, and restoration
- Standards development and validation
- Progress towards the actions recommended by the Government Accounting Office (GAO) in their March 2005 report, "*Anthrax Detection: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results.*"

In addition to its own expertise, DHS leverages resources of many other Federal departments and agencies. The Department of Defense (DoD) has had a robust biodefense program for many years and currently operates biodetection systems at several military installations. Following the 2001 anthrax attacks, the United States Postal Service (USPS) instituted their Biohazard Detection System (BDS) throughout components of the postal system. The Department of Health and Human Services' (DHHS) Centers for Disease Control and Prevention (CDC) provides medical response and public health guidance and protocols, while the Environmental Protection Agency (EPA) has extensive experience in remediation and associated methodologies, and the Department of Justice (DOJ) Federal Bureau of Investigation (FBI) is responsible for the criminal and forensic investigations. This list, which is not meant to be inclusive, demonstrates the depth and breadth of the national effort and the need for coordination and standards.

BIOLOGICAL SURVEILLANCE AND DETECTION

Five years ago, the Federal government did not have a concerted, national surveillance effort for the detection of biological threat agents. Scenario driven systems studies have demonstrated that early detection of an attack will result in expedited medical intervention. DHS, in partnership with other agencies, has made several significant investments to provide biological protection to our nation's population:

- BioWatch, an environmental monitoring system that helps provide the earliest possible warning of a biological attack
- Biological Warning and Incident Characterization System (BWIC), an integrated civilian decision support system which aids local decision makers in interpreting the public health and national security significance of any BioWatch detection events

In 2003, BioWatch was deployed to approximately thirty major US cities and continues its operation today. BioWatch is led and funded solely by DHS, and is operated through close partnership with CDC, EPA, and FBI. Due to the immediate strategic national need to rapidly deploy the first BioWatch system, existing technologies and capabilities were chosen to fulfill this first generation (Gen 1) effort. Gen 1 was deployed to focus on detection of moderate to large aerosol releases of a biothreat agent. The requirement to provide increased environmental monitoring coverage to transportation hubs and critical facilities is being addressed through the second generation deployment of this system (Gen 2). However, the vision always has been to provide a still more affordable, fully integrated system with a shorter detection window and increased agent detection

capability. This vision is being realized through development and deployment of the third generation (Gen 3) system.

BioWatch Generation 1: The Gen 1 system works to provide distributed aerosol collection capabilities coupled with centralized laboratory analysis for a limited number of threat agents. This system is operated by the local environmental and public health staff and in essence, any results are owned by the local public health officer as they have responsibility for the local public health response.

BioWatch Generation 2: The Gen 2 system enhancement focuses on providing three to four fold increases in the number of collection sites, including the placement of collectors in key transportation hubs and critical facilities. The development of mature facility siting tools and high throughput detection assays are helping to facilitate this effort. At the discretion of the local officials, transportation hubs and other critical infrastructures can be selected for collector placement and integration into the local BioWatch network. Additional collectors are held in reserve by the cities for use at large events or other high profile venues at the discretion of local officials. By the end of FY2006, the top ten threat cities will have Gen 2 capability in place.

BioWatch Generation 3: Gen 3 will use cutting edge technology to provide an instrument that will allow for fully automated collection and detection on site. These fully autonomous detectors will remove the need for routine manual sample retrieval or transport to a CDC Laboratory Response Network (LRN) laboratory for agent detection. The attendant cost saving will enable a significantly increased number of collectors to be installed in thirty metropolitan areas in facilities and outdoor environments resulting in protection for approximately 50% of the U.S. population. A large portion of the Gen 3 development is encompassed in the Biological Autonomous Networked Detector (BAND) program. This program, which is on schedule, will be field tested in FY2007, and piloted in FY2008 for an initial deployment in FY2009. The BAND system will provide self contained sampling and analysis at the collection site with the same level of confidence or greater as is currently available with the existing BioWatch LRN laboratories. The results of the BAND system's analysis will be networked back to the BioWatch laboratory to alert the public health officer for any additional follow up. The BAND detector will provide detection capability for a greater number of threat agents (~20) in a shorter period of time to detection ($\leq$ 4 hours) than what is currently available with comparable or better false positive goals and requirements to the existing system.

BioWatch Guidance: The DHS, in partnership with and concurrence from CDC, EPA, and FBI, has developed the *BioWatch Preparedness and Response Guidance* document to address incident response and characterization following a verified BioWatch positive. This guidance is provided to each of the BioWatch localities to assist them in developing a Concept of Operations (CONOPS) that will meet their specific circumstances and needs. The Guidance document, which is divided into three sections, discusses preparedness, response, and environmental sampling strategies for biological threat agents and respectively are entitled, *Part I: BioWatch Preparedness*, *Part II: BioWatch Response*, and *Part III: BioWatch Environmental Sampling*. These documents were

completed in February 2004 for the Gen 1 BioWatch system and are in the process of being revised for the Gen 2 BioWatch enhancement (FY2006). Specifically, the section covering environmental sampling will provide detail on indoor sampling strategies and techniques and will be tailored for specific microorganisms .

Biological Warning and Incident Characterization System: While a verified BioWatch positive is able to provide information that the genetic material of an organism is present, additional information is needed before one can assess the environmental health or national security significance of such a result. Decisions regarding public health actions should be based on epidemiologic and laboratory information, potential threat information provided by the FBI, and on a thoughtful strategy of follow-up environmental sampling. Therefore, DHS designed and currently is in the process of deploying the Biological Warning and Incident Characterization (BWIC) system to assist in the integration of disparate information to enhance awareness of an evolving biological situation triggered by a BioWatch detection event. BWIC will help local agencies and decision makers to respond in a timely fashion with greater certainty by providing a more unified view of an event, analysis of available environmental and health surveillance data, potential response strategies (using local capabilities and CONOPS), and resource management tools to all approved users.

RESTORATION OF FACILITIES

DHS S&T has a goal, through its restoration research and development (R&D) strategy, to develop a scientifically defensible sampling strategy and plan prior to a possible biological attack. DHS currently is conducting a systems approach to restoration research activities through its Domestic Demonstration Application Program (DDAP) in collaboration with EPA and DHHS (CDC/NIOSH). Through the DDAP, we have developed a general Restoration Plan for an international airport following release of a biological agent. San Francisco International Airport was selected as the model airport during development of the plan to illustrate specific details.

The response phases to a biological event, as defined with interagency cooperation, are Notification, First Response, Characterization, Remediation/Clean-up, Clearance, and Reoccupancy. The focus of the plan is on consequence management activities associated with the Characterization, Remediation, and Clearance Phases. Crisis management activities associated with the Notification and First-Response Phases are also briefly discussed in the Plan.

- **Characterization Phase:** The focus is on identifying the biothreat agent through use of reliable detection equipment, performing characterization environmental sampling to determine the location and extent of contamination, and obtaining positive confirmation of the agent using a reliable laboratory. Using a weight of evidence decision process, environmental characteristics of the biothreat agent (such as its survivability on surfaces), as well as potential health consequences to humans and harm to the environment, are evaluated to determine what type and

degree of remediation are needed for the affected facility and what public health (medical) measures are needed for persons who were potentially exposed.

- **Remediation Phase:** The focus is on preparing and implementing detailed plans for remediation of contaminated areas. Remediation generally begins with source reduction, pre-cleaning surfaces, and site preparation. Scenario-specific decontamination reagents and delivery systems are selected, and all systems are pre-tested before implementing chemical treatments. Remediation ends when the treatment chemicals have been removed or neutralized and all related decontamination activities, including waste disposal, are complete.

- **Clearance Phase:** The focus is on collecting key data such as clearance environmental sampling results along with any additional remediation data that are needed, applying specific criteria to judge the effectiveness of the remediation process, and concluding that it is safe to reoccupy a facility and reestablish airport operations. All applicable sampling and operational data are reviewed and evaluated by appropriate experts. Decisions are made by key public health officials and/or government agencies before airport operations are resumed.

The Restoration Plan also provides detailed description of 1) Available Biological Sampling and Analysis Methods, 2) Considerations for Sampling Design, 3) Probability-Based Sampling, as well as 4) Annotated Characterization and Clearance Sampling Plan Templates.

Available Biological Sampling and Analysis Methods: Sample collection methods can be grouped into three broad types: bulk (accumulated surface dust, HVAC filters), surface (wipe/swab/vacuum), and air sample (cassette, impactor) collection. Each sample-collection type has specific advantages in particular applications. Since limited data was available on surface sampling methods (which were extensively used during the postal sampling events), the DHS S&T completed sampling efficiency studies in FY2006 on polyester/rayon blend wipes, polyester swabs, and a vacuum filter sock and the studies currently are undergoing peer review. This information is critical for establishing the appropriate sampling design. Sample extraction and analysis methods are described with a recommendation of utilizing the LRN laboratories which employ standardized methods across the network.

DHS also is investigating the use of native air samples (e.g., building HVAC filters, filter inserts) to provide geographically resolved data as a vital input to incident characterization following a biological detection event. Native Air Sample (NAS) collection strategies and protocols associated with these interior transportation facilities will be developed and documented. In the event of an single BioWatch positive (only one sampler has a positive response and all others in the area are negative), timely collection of corroborative samples from NAS HVAC filters, pre-emplaced filter inserts or environmental surface sources in the immediate vicinity of the positive BioWatch site could be used.

Two NAS environmental sample collection strategies, the radial ray and grid search methods, have been developed for incident characterization of an outdoor event. These strategies provide a systematic approach for gathering information needed for an initial outdoor incident characterization of the estimated scale and direction of the biothreat agent aerosol that is crucial for determining appropriate and effective public health response. Subsequently, attack assessment based on a detailed survey (using a variety of NAS sources), and mapping of the exposure and residual hazard areas, will be required to identify and manage post-attack residual public health hazards and appropriate mitigation and restoration efforts.

Considerations for Sampling Design: Two major types of environmental sampling are conducted during restoration activities. Characterization environmental sampling gathers information about the extent of contamination. Clearance environmental sampling assesses the success of decontamination. Through pre-planning, all of the physical aspects of a facility are understood and the area can be divided into sampling zones and units. This information can then be used to establish a grid-based sampling scheme which can be used with several methods for choosing sample locations: 1) exhaustive sampling which occurs when every sample that could possibly be collected is actually collected, 2) judgmental sampling (Targeted sampling & Biased sampling) is the practice of choosing to sample specific locations for specific reasons, and 3) random sampling (Random (only) sampling & Statistical sampling) which is any method that includes randomizing the sample locations.

An electronic data-collection and data-management tool featuring electronic facility drawings, bar code tracking, and data visualization tool (Building Restoration Operations Optimization Model [BROOM]) has been developed by DHS S&T in FY2005 and exercised by CDC NIOSH in FY2006 to aid with the sampling zone and method selection. The tool was developed to assist in gathering samples and automates the process of merging field data with laboratory results. Information such as location, sample type, surface type, surface orientation, surface area, and surface texture is recorded for each sample. BROOM provides visual maps which can aid in highlighting patterns of contamination, validation of a single dispersion model or selection among alternative dispersion models, and identification of approximate boundaries of contaminated areas.

Probability-Based Sampling: Probability-based sampling, also called statistical sampling, is appropriate for certain kinds of questions, hypotheses, and decisions. It refers to methods for choosing sample locations so that inference from the results can involve a probability or confidence statement. For example, decision-makers might want to be able to say, "We are 95% confident that less than 1% of the floor surface is contaminated (above some specified level)." Risk-based limits for measurable *Bacillus anthracis* concentrations on surfaces do not exist at present, but if they were developed in the future for *B. anthracis* or some other biothreat agent, then statistical methods would be appropriate for testing hypotheses such as, "The average concentration of the agent on this surface is below x" (where x is a specified number in appropriate units), or "We are 95% confident that at least 98% of the surface has a concentration below x".

Because probability-based sampling uses random sampling, it is unlikely that many samples will be collected in atypical locations. It is highly unlikely, for example, that all samples will be collected in areas with the lowest concentrations, thereby failing to discover the magnitude of contamination. A sufficient number of randomly located samples will have a distribution of concentrations similar to that of the entire area being sampled, and the results will be representative.

In the context of airport restoration after a biological attack, probability-based methods are most likely to be appropriate for the assessment of relatively large surface areas where there is little information to indicate where contamination is likely (or unlikely) to be present. In FY2005, DHS sponsored a program, Visual Sample Plan (VSP) Module, through the Technical Support Working Group (TSWG) for statistically sampling buildings. This program developed statistical methods for quantifying the increased confidence one has when both judgment (biased) and probabilistic samples are utilized to demonstrate cleanliness of an area. The VSP has been evaluated by the responder community and version 4.4 is available on the internet for direct application (www.dqo.pnl.gov). DHS S&T plans to study the utility of this tool for wide area restoration starting FY2006.

Annotated Characterization and Clearance Sampling Plan Templates: The sampling plan templates are based on prior restoration efforts and required information in order to determine the area of contamination and success of decontamination. Sampling methods, qualified laboratories, and sampling design should be pre-determined with the assistance of subject matter experts.

Sampling and detection are integral parts of the response phases following a biological attack. The Characterization and Clearance phases are dependent on the selection of appropriate sampling designs which are scenario and goal dependent. In light of this, much of the effort of the DHS Restoration DDAP has been focused on sampling methodologies such as developing the BROOM and VSP tools. Annotated Characterization and Clearance Sampling Plan Templates have been developed for pre-planning the response to a biological attack. The Restoration Plan has been developed and reviewed in collaboration with EPA, CDC, and DoD. The restoration plan template for airports currently is in DHS and EPA agency final review for approval for public release and will be available in FY2006.

The Airport Restoration Plan currently is being leveraged to develop specific plans for Transit facilities. Washington Metropolitan Area Transit Authority (WMATA) and New York's Metropolitan Transportation Authority (MTA) were selected as the example transit facilities during development of the plan to illustrate specific details. DHS has initiated a Wide Area Restoration DDAP which will build off of the Airport and Transit facility Restoration Plans and continue to address associated sampling and detection issues following a large scale outdoor biological attack. It is envisioned that this type of attack will not only affect the complex outdoor environment but will also affect a large number of facilities (indoor environments). In order to conduct a Wide Area Restoration

Demonstration Program, DHS will be relying heavily on partnerships (State & local) and collaborations with various Departments and Agencies (EPA, HHS/CDC, DoD).

LEADERSHIP AND COORDINATION OF INTERAGENCY EFFORTS

DHS has been proactive in leading, co-leading, and coordinating interagency efforts associated with biological detection and restoration. Several of these efforts have been formalized by the Homeland Security Council, the National Science and Technology Council, while others are generated through the identification of a need to fill a critical biodefense gap. Aside from ongoing agency to agency discussions, DHS is leading and coordinating the following biodefense efforts which have sampling as a critical component:

- Memorandum of Understanding for Coordinated Monitoring of Biological Threat Agents
- Integrated Consortium of Laboratory Networks
- Postal and Shipping Integrated Project Team
- Subcommittee of Decontamination Standards and Technology
- Sponsorship of the National Conference on Environmental Sampling for Bio-Threat Agents

Memorandum of Understanding for Coordinated Monitoring of Biological Threat Agents: Under the aegis of HSPD-10, DHS has led the formulation of a Memorandum of Understanding (MOU) amongst DHS, DoD, DHHS, USPS on Coordinated Monitoring of Biological Threat Agents. This MOU has been finalized and agreed to by all the Parties. This MOU provides for 1) the development of an integrated system design and CONOPS, 2) the development of shared rapid notification protocols, 3) the establishment of assay equivalency (sensitivity and false positive rates) amongst the assays used by the Parties, 4) the development of a shared technology roadmap to commonly leverage advances in technology in a way compatible to the needs of all Parties, and 5) a strategy to extend the national monitoring concepts to other systems, such as other homeland security and related biodetection systems. The national biomonitoring architecture, which currently is in draft form, recommends that an integrated national biomonitoring architecture be based on three pillars: 1) standardized and validated detection techniques, 2) consistent detection, notification, and incident characterization protocols, and 3) maximization of synergy amongst the various elements. Consensus standards and an interim process for assay evaluation and validation will be completed and piloted in 2006. Development of consistent CONOPS for biological monitoring, to include mail and mail processing, is underway in the National Capital Region (NCR) and expected to be completed later this year.

Integrated Consortium of Laboratory Networks: Through a Memorandum of Agreement (MOA) with USDA, Department of Commerce (DOC), DoD, Department of Energy (DOE), DHHS, Department of the Interior (DOI), DOJ, Department of State (DOS) and EPA, DHS is leading an effort to establish an Integrated Consortium on Laboratory Networks (ICLN). The various agencies worked together to create the ICLN with the purpose of developing an organizational framework that links existing and future

laboratory networks under a single interagency umbrella to provide timely, high quality, and interpretable results for early detection and effective consequence management of acts of terrorism and other events. This integrated nationwide consortium of laboratory networks is needed to support the delivery of timely, high quality, and interpretable results through: 1) inter-network communication and information sharing, 2) resource optimization, 3) resource coordination, 4) accountability, and 5) strategic planning. Additionally, this ICLN will create an inclusive forum for Federal leadership to share ideas, work collaboratively, and build relationships that will support a more effective integrated response during emergencies.

The ICLN currently is performing a capability assessment, facilitated through the Homeland Security Institute (HSI), which uses nine scenarios to specifically challenge the ICLN networks. For example, the "Anthrax in an Urban Environment" scenario challenges multiple laboratory networks: CDC's LRN, which currently analyzes all sample types including clinical specimes, food, water, and environmental samples, and EPA's proposed environmental Laboratory Response Network (eLRN), which is primarily focused on developing capacity for chemical warfare agent testing in environmental samples, are actively involved. The results of the ICLN Capability Assessment study will help to give a much better understating of the sample analysis capacity in our Nation's laboratories. Any resulting gaps between the sample analysis demands and current capacities can then be better addressed with a more focused approach to solving this problem. The preliminary results to the ICLN Capability Assessment study will be reported to DHS in July 2006.

Postal and Shipping Integrated Project Team: DHS has also established, for Postal and Shipping, an Integrated Project Team (IPT) which includes representatives from USPS, DoD, DOJ, and GSA. Following the anthrax attacks in 2001, several Federal agencies implemented additional mail screening to include parcels and mail delivered by commercial carriers. An effort is underway to standardize Federal mail screening processes, preferably through a common mail screening facility to assure that standardized methods are employed and to reduce screening associated costs. Discussions currently are underway to implement this approach in the National Capital Region (NCR) and then nationally.

Subcommittee on Decontamination Standards and Technology: DHS is co-chairing, with EPA, the Subcommittee on Decontamination Standards Technology (SDST) assembled by the National Science and Technology Council's Committee on Homeland and National Security. The subcommittee, comprised of all Federal departments and agencies that have restoration related technology or research and development activities, is charged to facilitate the development of consistent guidelines and strategies to address decision making regarding decontamination after a chemical or biological incident. The objectives of this Subcommittee are two-fold: 1) to develop a scientifically-based risk management approach for decontamination standards applicable to a wide array of biological and chemical terrorism event scenarios, and 2) develop a coordinated R&D strategy and budget initiative to address gaps in decontamination technology

development necessary for the decontamination of open and urban (indoor and outdoor) environments after an attack using biological or chemical weapons.

One key piece of the decontamination process under consideration by the committee is sampling strategies and technologies. Guidelines for biological and chemical restoration currently are under review and an overarching chemical, biological, radiological and nuclear (CBRN) document is in preparation. The intended audience of the guidance document is local decision makers and on-scene coordinators and incident commanders.

The Coordinated Biomonitoring MOU, Integrated Consortium of Laboratory Networks MOU, Postal and Shipping IPT, and SDST subcommittee are all efforts to coordinate current biological agent sampling, monitoring, and restoration efforts conducted by various agencies. Although surface sampling is not the initial focus of these efforts, they are addressing the issues of validation, performance characteristics, interpretation of results, investment strategies, and policies as agreed upon by the interagency group. Once consensus is reached with current biological agent monitoring, the foundation will be laid to address other issues such as surface sampling.

Sponsorship of the National Conference on Environmental Sampling for Bio-Threat Agents: In addition, DHS is participating in the R&D and responder communities to address environmental sampling efforts that are applicable to biological surveillance and restoration. DHS co-sponsored, with DoD, the first National Conference on Environmental Sampling for Bio-Threat Agents in January 2005. As part of the conference, current R&D activities evaluating sampling methodology performance were identified. In addition, several sessions were held to discuss the need for consensus on standardized sampling approaches amongst the agencies. As a result of the meeting, DHS partnered with the National Institute of Standards and Technology (NIST), to gather key stakeholders together to develop a national standard for sampling of suspicious powder (described below). Due to the success of the first conference, DHS will co-sponsor the Second National Conference on Environmental Sampling for Bio-Threat Agents in October 2006 to foster collaboration and technology exchange among the research and responder communities in government, industry and academia.

STANDARDS AND VALIDATION

The first step towards validation must involve defining the necessary requirement for the sampling process or methods in specific scenarios, developing standards or minimum performance characteristics as needed, and initiating testing and evaluation to verify that those requirements are met. The Standards Portfolio within DHS S&T has a mission to develop and coordinate the adoption of national standards and the appropriate evaluation methods to meet homeland security needs.

Sampling Suspicious Powders: In FY2005, DHS in collaboration with NIST, took the first steps to prioritize and initiate the development of standards related to biological sampling activities. An American Society for Testing and Materials (ASTM) standard

was drafted to standardize and validate the method by which hazardous materials technicians collect, transport, and store suspicious powder samples. We are in the final stages of this multi-agency effort to provide a standard for visible powder sample collection that reflects the consensus of many agencies, including the FBI, CDC, EPA, and DoD. The collaborative study to validate the sample collection standard for visible powders was completed last month at Dugway Proving Grounds in Utah, and the data are being compiled into a final report for review and if appropriate, approval by the AOAC INTERNATIONAL experts next month. AOAC INTERNATIONAL, the independent, third-party scientific association well-known for its "Gold Standards," is collaborating with ASTM on the sample collection standard, and based on preliminary review, it seems fair to say that this AOAC/ASTM standard will soon be available for use by trained first responders.

Public Health Actionable Assays: As stated above, the national biomonitoring architecture requires standardized methods for biological detection assays. In FY2006, DHS, in collaboration with our interagency partners, will develop, evaluate, validate and make available an assay set of high sensitivity, high specificity, real-time PCR primers and probes or immunoassay antibodies for use by the private sector that develops commercial off-the-shelf biodetection technologies. The program will be piloted in FY2007. This will provide rapid detection capability with a high level of confidence for several biological threat agents, to include *B. anthracis*. These detection assays will be validated in partnership with industry and the validation process transitioned to the commercial sector for future assay validation efforts. As stated above, these foundational processes established in this effort will provide a framework for future validation efforts for detection-related methods.

CONCLUSION

In March 2005, the GAO submitted a report to this Subcommittee entitled, "*Anthrax Detection: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results.*" The GAO was charged by this Subcommittee to describe and assess federal agencies' activities to detect anthrax in postal facilities, assess the results of agencies' testing, and to assess whether agencies' detection activities were validated. DHS concurs with the GAO that use of stratified and probabilistic "sampling strategies, together with validated methods for detecting contamination, would provide a known level of confidence with which to interpret any negative results and would thus enable agencies to be more definitive in determining necessary actions." Their investigation prompted valid recommendations of which DHS has made significant progress in addressing:

- DHS has taken a lead role in promoting and coordinating the activities of various agencies that have technical expertise related to environmental testing:
    - DHS led the formulation of a Memorandum of Understanding (MOU) amongst DHS, DoD, DHHS, USPS on Coordinated Monitoring of Biological Threat Agents and is leading the MOU execution.
    - DHS is leading an effort to establish an Integrated Consortium on Laboratory Networks (ICLN).

    - DHS has established a Federal Postal and Shipping Integrated Project Team.
    - DHS is co-chairing the Subcommittee of Decontamination Standards Technology.
    - DHS is co-sponsoring the Second (and First) National Conference on Environmental Sampling for Bio-Threat Agents.
- DHS has adopted the international quality management standard ISO 1901 definition of validation.
- DHS has developed a process to standardize and validate methods:
    - DHS has validated a method for sampling of suspicious powders.
    - DHS is in the process of developing a method for the validation of public health actionable assays.
- DHS has invested both in targeted and probabilistic sampling strategies and as well as methodologies that are appropriate for facility monitoring and applicable to wide area and facility restoration. R&D efforts include:
    - Performance characterization of 3 sampling methods on varied surfaces.
    - Development of the Building Restoration Operations Optimization Model (BROOM).
    - Sponsorship of the Visual Sample (VSP) Module.
    - Development of the Annotated Characterization and Clearance Sampling Plan Templates for pre-planning the response to a biological facility attack.
    - Development of *BioWatch Preparedness and Response Guidance*, which includes *Part III: BioWatch Environmental Sampling.*
    - Developing native air sample collection strategies and protocols associated with transportation facilities.
- DHS has prioritized investments for high risk biological agents through internal and interagency coordination to include:
    - SDST R&D Investment Strategy.
    - Agency to agency discussions on leveraging R&D opportunities
    - Internal strategic planning and requirements generation.

The March 2005 GAO report focuses on the statistical confidence associated with environmental sampling strategies and methodologies. Sampling is an integral part of a larger system such as biological surveillance and restoration and thus, the requirements generated for sampling performance (e.g., limit of detection, sensitivity, specificity, tolerance) should be determined within the context of the system. Furthermore, other aspects such as economics, capacity, public perception, decontamination goals, etc. should be factored into the decision making process to use particular sampling strategies. Understanding how to use scientifically based information and methodologies within the context of a biosurveillance or restoration framework will provide for higher confidence decisions in a realm of uncertainty.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Ranking Member Kucinich, and Members of the Committee, I thank you for the opportunity to appear before you.